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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/696,982	10/27/2000	F. Richard Bringhurst	0609.4430001/JAG/CMB	1728

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EXAMINER

ULM, JOHN D

ART UNIT	PAPER NUMBER
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1646

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DATE MAILED: 02/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/696,982

Applicant(s)
Bringhurst et al.

Examiner
John Ulm

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Nov 20, 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2 and 6-8 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2 and 6-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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- 1) Claims 2 and 6 to 8 are pending in the instant application. Claim 2 has been amended as requested by Applicant in Paper Number 10, filed 21 October of 2002.
- 2) Any objection or rejection of record which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.
- 3) The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
- 4) A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 20 November of 2002 has been entered.
- 5) Claims 2 and 6 to 8 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 2 of U.S. Patent No. 6,183,974 because the claimed subject matter in the patent is encompassed in its entirety by the instant claims. As stated previously, Applicant's arguments in traversal of this rejection are not persuasive because a generic claim is always obvious over a species claim encompassed by that generic claim. Anything which anticipates a claim certainly renders that claim obvious. Therefore, an analysis of obviousness in accordance with 35 U.S.C. § 103 is inappropriate where the pending claims are anticipated by the patent claims. The rejection is maintained because

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Applicant has failed to identify that limitation in the instant claims which is not met by the patent claim.

Further, with respect to the newly added limitations to claim 2, the subject matter now claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter.

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application which matured into a patent. See MPEP § 804.

6) Claims 2 and 6 to 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 2 is vague and indefinite because there is no clear antecedent basis for “said cells of step (d)” because step “(d)” refers to two different populations of cells. It is unclear if the claim requires one to measure the activity of the “stably transfected cells”, the “cells of step (a)”, or both populations of cells. Claims 6 to 8 are vague and indefinite in so far as they depend from claim 2 for this element.

7) Claims 2 and 6 to 8 stand rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements for those reasons of record in section 4 of Paper Number 4. As stated therein, Applicant’s traversal of this rejection completely fails to explain how one can distinguish between a compound which effects either of the two measured pathways directly or through a mechanism

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other than a heterologous receptor and a compound which effects either of these pathways indirectly by activating or inhibiting the heterologous receptor of interest. Clearly some comparative step between a cell comprising the recombinant receptor and a cell lacking that receptor would be a minimal requirement for the claimed method to meet its functional requirements. Applicant can not rely upon what is known in the art to complete the instant claims. It is precisely because one of skill would recognize that the claimed method can not achieve its stated objective without a comparative step that the instant rejection was made. Applicant's assertion that one of ordinary skill would know to perform the appropriate controls only supports the propriety of the instant rejection. This rejection is maintained because these claims, as amended, still do not contain a comparative step.

8) Claims 2 and 6 to 8 stand rejected under 35 U.S.C. 101 because the disclosed invention is inoperative and therefore lacks utility. Because the claimed invention is incomplete for those reasons given under 35 U.S.C. 112, second paragraph, above, it is inoperative.

9) Claims 2 and 6 to 8 stand rejected under 35 U.S.C. 103(a) as being unpatentable over the Catanzariti et al. publication (BioTechniques 15(3):474-479, Sep. 1993) in view of the combination of the Segre et al. patent (5,494,806) and the Bringham et al. publication (Endocrinology 132(5):2090-2098, May 1993) for those reasons of record in section 6 of Paper Number 4. Applicant is advised that the office action mailed on 02 November of 2001 is Paper Number 4, as indicated at the bottom of the "**Office Action Summary**" (PTO-326) attached thereto.

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Contrary to Applicant's assertion, the instant rejection is not based upon a premise that the instant "invention is inherent to the assay of Bringhurst". The instant rejection is based upon a premise that the limitation "a receptor which couples to both Gs and Gq proteins" is inherent to the human parathyroid hormone/parathyroid hormone related peptide receptor (PTHrP) of the Segre et al. patent as demonstrated by the fact that this is the only receptor described in the instant specification.

The instant rejection is maintained because the Bringhurst et al. publication disclosed the production of LLC-PK1 cells which were stably transfected with DNA encoding rat and opossum PTHrPs for the purpose of identifying agonists and antagonists thereto, the Segre et al. patent described an isolated DNA encoding a human homolog of the rat and opossum PTHrPs of Bringhurst et al. and expressly identified the LLC-PK1 cell line as one of five preferred cell lines for the recombinant expression of the PTH/PTHrP receptor described therein, and because Catanzariti et al. described a method of "rapidly" identifying LLC-PK1-derived cell lines expressing heterologous receptors that couple to G_s-proteins by transfecting LLC-PK1 cells with DNA encoding a heterologous G protein-coupled receptor and screening for ligand-induced, cyclic AMP-mediated urokinase activity. The Bringhurst et al. and Segre et al. references provided ample motivation to express the human PTHrP receptor of Segre et al. in LLC-PK1 cells as described by Bringhurst et al. for the purpose of identifying agonists and antagonists thereto and Catanzariti et al. provide the motivation to measure the activation of that human receptor in that cell line by measuring ligand-induced, cyclic AMP-mediated urokinase activity. Because the

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instant specification shows that the PTHRs of Bringhurst et al. and Segre et al. were inherently coupled to both Gs and Gq proteins when expressed in LLC-PK1 cells, this combination of references taught all of the limitations of the instant claims either explicitly or inherently, and provided ample explicit motivation to combine those elements in the manner claimed.

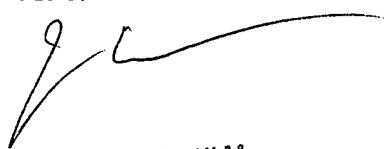
10) Applicant's arguments filed 21 October of 2002 and 20 November of 2002 have been fully considered but they are not persuasive for those reasons given above.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (703) 308-4008. The examiner can normally be reached on Monday through Friday from 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4242 or (703) 872-9306. Official responses under 37 C.F.R. § 1.116 should be directed to (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



JOHN ULM
PRIMARY EXAMINER
GROUP 1800